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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,925	01/29/2002	Kevin R. Heath	BSI-491US	9741

7590 09/30/2004

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/059,925	Applicant(s) HEATH ET AL.	
	Examiner Leslie R. Deak	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
 4a) Of the above claim(s) 26-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/6/02, 6/7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings are generally inconsistent and unclear. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 13, 16-18, 19-22 24, 25 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,681,570 to Dalton. Dalton discloses a helically shaped catheter with several openings in the sidewall that are arranged on the inside and outside of the helix, and may be considered a helical pattern. The catheter, formed of a suitable biocompatible thermoformable elastomer, is about 0.5cm in diameter, with a helix diameter of about 1.0 cm that ends with the catheter pointed in an axial direction. See FIG 1, column 3. With regard to applicant's recitation drawn to the use of the catheter in a particular manner (such as a perfusion or hemodialysis catheter), such limitations

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amount to the intended use of the device. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-11, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,681,570 to Dalton in view of US 4,795,439 to Guest. Dalton discloses the apparatus as claimed with the exception of a multi-lumen catheter wherein the lumens are arranged in a helical pattern within the catheter. Guest discloses a catheter with septums that divide the catheter into two or more lumens, with openings in the sidewall for each lumen. The lumens wind helically around the interior of the catheter in order to prevent an entire lumen from being occluded when deployed against a vessel wall. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add helically-wound multiple lumens as disclosed by Guest to the helically wound catheter as disclosed by Dalton in order to prevent an entire side of the catheter from being occluded in case it is deployed against a vessel wall. With regard to the direction in which the catheter points at its distal end, absent any showing of criticality, the direction of the distal tip is a matter of obvious design choice.

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,681,570 to Dalton in view of US 4,795,439 to Guest, further in view of US 5,190,520 to Fenton, Jr. et al. Dalton and Guest disclose the catheter as claimed with the exception of one lumen extending farther than another and the reinforcing structure. Fenton illustrates that one lumen extends farther than the other in the distal end of the catheter. The catheter further comprises a reinforcing structure as one of the layers in its construction. This configuration aids more efficient and collapse-resistant fluid transfer. See FIG 1. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a reinforcing structure and a formed tip on the catheter in order to more efficiently transport blood and prevent catheter collapse, as taught by Fenton.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

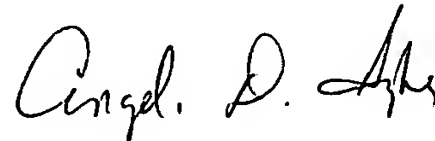
- a. US 4,694,838 Wijayarthna et al
- i. Looped catheter

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 703-305-0200. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lrd
21 September 2004


**ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700**